February 27, 2024

Solco Biomedical Copany India Private Limited
Darshak Shah
Director
Survey No.1540, Beside Torrent Pharma,
Village-Rajpur Ahmedabad Mehsana Highway
Kadi, Gujarat/ Mehasana 382715
India

Re: K232607
Trade/Device Name: 4CIS SARA SPINE SYSTEM, 4CIS VERTU SPINE SYSTEM, 4CIS WILL PEDICLE SCREW SYSTEM, aBle SPINAL FIXATION SYSTEM, aBle Xt SPINAL FIXATION SYSTEM
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: January 29, 2024
Received: January 29, 2024

Dear Darshak Shah:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232607

Device Name
4CIS SARA Spine System, 4CIS VERTU Spine System
4CIS WILL PEDICLE SCREW SYSTEM
aBle SPINAL FIXATION SYSTEM, aBle Xt SPINAL FIXATION SYSTEM

Indications for Use *(Describe)*

The 4CIS SARA Spine System , 4CIS VERTU Spine System, aBle SPINAL FIXATION SYSTEM, aBle Xt SPINAL FIXATION SYSTEM and 4CIS WILL PEDICLE SCREW SYSTEM are the pedicle screw systems indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-Sl vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The 4CIS SARA Spine System , 4CIS VERTU Spine System, aBle SPINAL FIXATION SYSTEM, aBle Xt SPINAL FIXATION SYSTEM and 4CIS WILL PEDICLE SCREW SYSTEM are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

aBle Xt SPINAL FIXATION SYSTEM and 4CIS WILL PEDICLE SCREW SYSTEM are intended to used for Minimal Invasive Surgery (MIS).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SOLCO.	SOLCO BIOMEDICAL COMPANY INDIA PRIVATE LIMITED	
	DOC NO: K202498/Summary REV. NO : 1.0	PAGE NO 1 of 4
TITLE: 510(k) Summary		

"510(K) SUMMARY"

This summary of 510(k) substantial equivalence information is being submitted in accordance with requirement of 21 CFR 807.92.

Submitter	SOLCO Biomedical Company India Private Limited Survey No.1540, Beside Torrent Pharma, Village-Rajpur Ahmedabad Mehsana Highway, Ta-Kadi, Dist-Mehsana Gujarat- 382715, INDIA. Tel : +91 851112597, Email: darshak@solco.co.in
Contact Person	Darshak Shah- Director SOLCO Biomedical Company India Private Limited Phone : +91 98252 06091, Email: darshak@solco.co.in
Submission Date	24 FEB 2024.
Trade / Proprietary name	4CIS SARA Spine System 4CIS VERTU Spine System 4CIS WILL PEDICLE SCREW SYSTEM aBle SPINAL FIXATION SYSTEM aBle Xt SPINAL FIXATION SYSTEM
Classification Name Classification Code Regulatory Class Regulation Number	Thoracolumbosacral Pedicle screw system NKB Class II 888.3070
Primary Predicate Device	

510K Number	Trade or Property or model Name	Manufacturer
K202498	4CIS SARA Spine System 4CIS VERTU Spine System	SOLCO Biomedical Company India Private Limited

SOLCO.	SOLCO BIOMEDICAL COMPANY INDIA PRIVATE LIMITED	
	DOC NO: K202498/Summary NO : 1.0 REV.	PAGE NO 2 of 4
TITLE: 510(k) Summary		

Description of Device	The Spinal Fixation System is a top-loading posterior spinal fixation system which consists of pedicle screws, rods, and nuts, transverse (cross) link and associated instruments. Rigid fixation is provided by pedicle screws inserted into the vertebral body through pedicle of the lumbar spine via posterior approach. This system will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion through open surgery. Implant components can be rigidly locked into a variety of different configurations to suit the individual pathology and anatomical conditions of the mature patient. The implant components are supplied non-sterile single use and are fabricated from titanium alloy (Ti-6A1-4V ELI) and Cobalt Chromium ally that conforms to ASTM F136 and ASTM F1537 respectively. Also, Specialized instruments are available for the application and removal of the Spinal Fixation System.
Indication for Use	The 4CIS SARA Spine System , 4CIS VERTU Spine System, aBle SPINAL FIXATION SYSTEM, aBle Xt SPINAL FIXATION SYSTEM and 4CIS WILL PEDICLE SCREW SYSTEM are the pedicle screw systems indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-SI vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. The 4CIS SARA Spine System , 4CIS VERTU Spine System, aBle SPINAL FIXATION SYSTEM, aBle Xt SPINAL FIXATION SYSTEM and 4CIS WILL PEDICLE SCREW SYSTEM are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or

	deformities of the thoracic, lumbar and sacral spine: degenerative Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). aBle Xt SPINAL FIXATION SYSTEM and 4CIS WILL PEDICLE SCREW SYSTEM are intended to used for Minimal Invasive Surgery (MIS).
Comparison of Technological Characteristics with the Predicate Devices	The 4CIS WILL PEDICLE SCREW SYSTEM, aBle Xt SPINAL FIXATION SYSTEM & aBle SPINAL FIXATION SYSTEM have similar indications as compare to cleared 4CIS SARA Spine System and 4CIS VERTU Spine System. The system is composed of the same material as the predicate-K202498 devices conforming to recognized industry standards for permanent implants (titanium alloy (Ti-6A1-4V ELI) that conforms to ASTM F136) and surgical orthopedic instruments. aBle SPINAL FIXATION SYSTEM is modified version of 4CIS SARA Spine System and 4CIS VERTU Spine System which does not raise any concern of safety and performance. 4CIS WILL PEDICLE SCREW SYSTEM is intended to used for Minimal Invasive Surgery (MIS). Also they are provided non-sterile for single use only.
Performance Data	Mechanical testing (static and dynamic compression bending, static tension bending, static torsion) is conducted in accordance with ASTM F1717 on the worst case construct. Static Compression Bending, Dynamic Compression Bending, Static Torsion, and Static Tension tests results meet performance requirement against predicates.
Biocompatibility	The subject implants are permanent implants (> 30 days) and are classified as body contacting devices according to FDA's Draft Guidance for Industry

	and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." The subject implants are **manufactured from identical materials** as the predicate devices, **in accordance with the ASTM F136** – Standard Specification for Wrought Titanium – 6Aluminum – 4Vanadium ELI (Extra-Low-Interstitial) Alloy for Surgical Implants **The materials used for manufacturing the subject device have a long history of safe and effective use identical to predicate devices and biocompatibility testing is not required.**
Conclusion	The overall technology characteristics, material of construction , design characteristics and performance data lead to the conclusion that our Spine Systems (4CIS SARA Spine System , 4CIS VERTU Spine System, aBle SPINAL FIXATION SYSTEM, aBle Xt SPINAL FIXATION SYSTEM and 4CIS WILL PEDICLE SCREW SYSTEM) are substantially equivalent to our FDA previously cleared devices of K202498 for intended use, material composition, principles of operation, and overall design.